

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 6180  |
| <b>2: Name of authorisation holder</b>  | SYNERGY HEALTH STERILISATION UK LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | SYNERGY HEALTH STERILISATION UK LIMITED , MORAY ROAD,<br>ELGIN INDUSTRIAL ESTATE, SWINDON, SN2 8XS, UNITED KINGDOM<br><br>SYNERGY HEALTH STERILISATION UK LIMITED , BRUNEL CLOSE,<br>DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY, NN11 8RB,<br>UNITED KINGDOM<br><br>SYNERGY HEALTH STERILISATION UK LIMITED, ROYDSDALE WAY,<br>EUROWAY TRADING ESTATE, BRADFORD, BD4 6SE, UNITED<br>KINGDOM<br><br>SYNERGY HEALTH STERILISATION UK LIMITED, RENAISSANCE<br>HOUSE, 2200, BASING VIEW, BASINGSTOKE, RG21 4EQ, UNITED<br>KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  |   |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2   |
| <b>6: Legal Basis of authorisation</b>  | Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004<br>[SI 2004/1031]  |
| <b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b> | Confidential  |
| <b>8: Authorisation Date</b>  | 07/11/2022  |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2  |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**SYNERGY HEALTH STERILISATION UK LIMITED** , MORAY ROAD, ELGIN INDUSTRIAL ESTATE, SWINDON, SN2 8XS, UNITED KINGDOM

|   |
|---|
| Human Investigational Medicinal Products  |
| Authorised Operations   |
| MANUFACTURING OPERATIONS (according to part 1)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b> |

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.5 ] Gamma irradiation

## SCOPE OF AUTHORISATION

### Annex 2

Name and address of the site:

**SYNERGY HEALTH STERILISATION UK LIMITED**, BRUNEL CLOSE, DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY, NN11 8RB, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

#### Part 1 - MANUFACTURING OPERATIONS

##### [ 1.4 ] Other investigational medicinal products or manufacturing activity

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.5 ] Gamma irradiation

[ 1.4.2.6 ] Electron beam

## SCOPE OF AUTHORISATION

### Annex 2

Name and address of the site:

**SYNERGY HEALTH STERILISATION UK LIMITED**, ROYDSDALE WAY, EUROWAY TRADING ESTATE, BRADFORD, BD4 6SE, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

#### Part 1 - MANUFACTURING OPERATIONS

##### [ 1.4 ] Other investigational medicinal products or manufacturing activity

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.5 ] Gamma irradiation